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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/072,570

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Gijsbertus Johannes Van Oorschot

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EXAMINER

SULLIVAN, DANIELLE D

ART UNIT

PAPER NUMBER

1616

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/072,570	Applicant(s) VAN OORSCHOT ET AL.	
	Examiner DANIELLE SULLIVAN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-16, 19-24 and 27-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-16, 19-24 and 27-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner of this application has changed from Edward Webman to Danielle Sullivan who can be reached at 571-270-3285.

Response to Arguments

Applicant's arguments, filed 12/26/2007, with respect to the rejection(s) of claim(s) 11-28 under 35 USC §103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicant's amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-16, 19-21, 23, 24, 27 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632).

Applicant's Invention

Applicant claims a food product selected from the group consisting of a margarine, a dressing, a sweet, a cereal bar, a breakfast cereal and a beverage; said

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food product comprising an extract of a fermentation product formed by fermenting a substrate comprising more than 50% by weight of soy ingredients (preferable 80%) with a statins producing monascus ruber fungus; wherein the fermentation product comprises one or more statins and one or more polyphenols and has a Hue a* value less than 20; wherein said soy ingredients are selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes; and wherein said extract is an ethanol extract or an edible oil extract (preferably more than 10% of a vegetable oil).

The fact that fermentation product comprises statins and one or more polyphenols (comprising genistein and genistin) and has a Hue a* value less than 20 is treated as an inherent property of the soybean fermentation product (includes polyunsaturated fatty acids, phytosterols, proteins, peptides, dietary fibers and saponins) when *Monascus ruber* fungus is used. Therefore, for the purpose of examination, the fermentation product is treated as the product obtained from fermenting a substrate comprising more than 50% by weight of soy ingredients with a statins producing monascus ruber fungus.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Manzoni et al. teaches a method of screening *Monascus* and *Aspergillus* strains for statins production (abstract). The medium contained 3% whole or defatted soybean flour (page 254, column 1, paragraph 3). Statins could then be isolated by extraction with ethyl acetate (page, 254, column 1, paragraph 5). Once the quantitative assay

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procedure was established, fermentation experiments using strains of *Monascus* and *Aspergillus* were carried out and the whole soybean flour had a 40-41% protein and 22-24% lipid content, while the defatted flour 49-52% proteins and only 0.5%-1.5% lipid content (page 255, column 1, paragraph 2). Results show that the lipid content of the media influenced statin biosynthesis (page 257, column 1, paragraph 1). The amount of statins produced was effected by strain used and duration of fermentation (See Table 1). Manzoni et al. teaches that statin result in a decrease in cholesterol (page 253, column 2, paragraph 2).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Manzoni et al. do not teach a process of making a food product comprising and extract of the product obtained from fermenting a substrate comprising more than 50% by weight of soy ingredients. However, in view of In re Auller, Lacey and Hall, 105 USPQ 233 (C.C.P.A. 1955), it is normal practice to change concentration to increase the degree of results obtained. Therefore, increase the amount of soybean flour would increase statins production.

Manzoni et al. do not teach that the process is used in the formulation of a food product. It is for this reason that Zhang et al. is joined.

Zhang et al. teach a method of fermenting red rice with *Monascus* in order to formulate a dietary supplement or medicament for the treatment of high cholesterol in humans (column 4, lines 5-18).

Manzoni et al. do not teach that the extract is an ethanol or edible oil. It is for this reason that Chaihorsky et al. is added.

Chaihorsky et al. teaches that isoflavones have been isolated from soybean plants for use as dietary supplements and include isoflavones in a glucone form such as genistein and genistin (column 1, lines 14-23). Typically, the isoflavones are eluted by a polar solvent such as methanol or ethanol (column 1, lines 60 and 61).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to adjust the amount of soybeans and the strain of *Monascus* in order to obtain a food product comprising a dietary supplement having variable amounts of statins and polyphenols, such as genistein and genistin. One would have been motivated to include adjusting the fermentation process because this is routine optimization and would be useful in allowing for an increased yield of statins and polyphenols produced from a smaller amount of ingredients. Increasing the amount of soybeans would aid in producing more fermentation product, while adjusting the strain of *Monascus* would influence the amount of statins produced within a given period of time.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manzoni et al. and Zhang et al. to further include a food product obtained from fermenting a substrate comprising more than 50% by

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weight of soy ingredients with a statins producing monascus ruber fungus. One would have been motivated to manufacture a food product from fermented soybeans with Monascus because statins are known to aid in decreasing cholesterol and can therefore be beneficial dietary supplements. Also, having more than 50% by weight of soy ingredient would ensure a large yield of statins are produced.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manzoni et al., Zhang et al. and Chaihorsky et al. to further include extracting the fermentation product with ethanol. One would have been motivated to include ethanol because it is used to concentrate isoflavones from soybeans. Therefore, using ethanol would allow for the polyphenols (isoflavones) to be isolated from the fermentation product.

Claims 22, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manzoni et al. (Production of statins by filamentous fungi, 1999), Zhang et al. (US 6,046,022) and Chaihorsky (US 5,670,632) in further view of Zilliken (US 4,218,489).

Applicant's Invention

Applicant claims the product addressed in above 35 U.S.C. 103(a) rejection wherein the extract is an edible oil extract (preferably more than 10% of a vegetable oil).

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Manzoni et al., Zhang et al., and Chaihorsky as addressed in above 35
U.S.C. 103(a) rejection.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Manzoni et al., Zhang et al., and Chaihorsky do not teach an extract of an edible vegetable oil. It is for this reason that Zilliken is added.

Zilliken teach antioxidant food composition with isoflavones (abstract). Zilliken teach that vegetable oils protect isoflavones or their extracts from oxidation (column 7, lines 46-51).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Manzoni et al., Zhang et al., Chaihorsky et al. and Zilliken to further include extracting the fermentation product with vegetable oil. One would have been motivated to include vegetable oil because it protects food from oxidation thus increasing antioxidant effectiveness. This would aid in the preservation of the fermentation product contained in the food product and allow for more of the beneficial statins and polyphenols to be consumed by the patient in need of the cholesterol lowering effect.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
Art Unit 1616

/Mina Haghighatian/
Primary Examiner
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